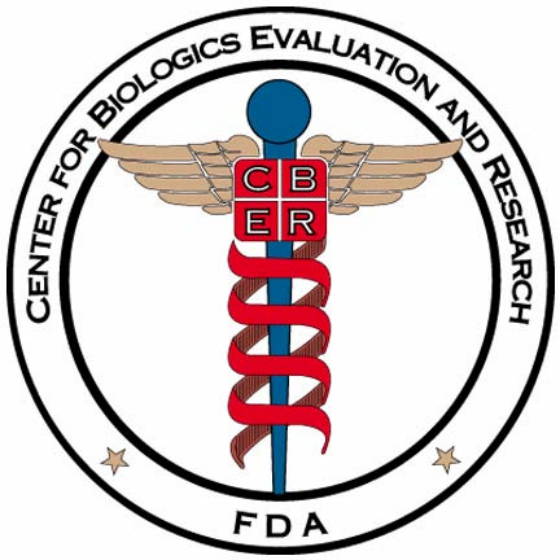

The Development of FDA Regulations and Guidance Documents

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OVERVIEW

- Legal Framework
- Rulemaking
- Guidance Documents

LEGAL FRAMEWORK

- **CONSTITUTION**
- **STATUTES**
- **REGULATIONS**
- **GUIDANCE**

STATUTES

- **PUBLIC HEALTH SERVICE ACT**
  - licensing provisions
  - prevent communicable disease
- **Federal Food, Drug and Cosmetic Act**
- **Other Statutes**
  - e.g. Administrative Procedure Act
  - Federal Advisory Committee Act

RULEMAKING AND POLICY: BASIS FOR REGULATORY DECISIONS

- **Rule- "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy"**
- **Has binding effect**
- **We create rules under statutory authorities (PHS Act and FDC Act)**

Rulemaking Considerations

- Rules – way to establish requirements
- When might we write rules-
  - We want to create clear requirements
  - Congress requires it (e.g. FDAMA- ggps)
  - Oversight committees/industry/consumers point out need

Notice and Comment Rulemaking

- **Minimum requirements**
  - Publish notice of proposed rule
  - Opportunity for public participation by written comments
  - Publish final rule and statements of basis and purpose not less than 30 days before effective date
- **Final Rule**
  - Includes codified text
  - Preamble – discuss background, major issues, and responses to substantive comments received

Proposed Rule
What goes in the Federal Register

- **Agency: FDA**
- **Action: Proposed Rule**
- **Summary: The FDA proposes to amend …..**
- **Dates: Submit comments by …….**
- **Addresses: Submit comments to …….**
- **For Further Information Contact: Contact name**

Proposed Rule
What goes in the Federal Register

- **Supplementary Information:**
  - I. Background
  - II. The Proposed Amendments
  - III. Federalism
  - IV. Paperwork Reduction Act of 1995
  - V. Analysis of Impacts
  - VI. Request for Comments
  - Actual regulation language

Advantages of Rulemaking

- **Wider notice and opportunities for participation**
  - **Transparency for all affected**
  - **More efficient (due to broad participation and info gathering)**
- **Better means of making new law because it's prospective**
- **Provides greater clarity to those affected and uniformity in enforcement**

Advantages (cont'd)

- **Efficiency -can be applied without reexamination**
- **Has the force and effect of law**

Disadvantages of Rulemaking

- Procedural complexities (e.g., paperwork review, OMB review, impact statements)
- Modifications can't be made quickly
- May cause conflict/controversy
- Potential for over- or under-inclusiveness
- Difficult to develop generalized standards

Good Guidance Practices

(Title 21 Code of Federal Regulations (CFR) 10.115(a))

- GGP's are FDA's policies and procedures for developing, issuing, and using guidance documents
- Purpose – to make our procedures clear to public
- Regulated persons may chose an alternative approach that complies with laws and regulations

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Good Guidance Practices

What is a Guidance Document? (21 CFR 10.115(b))

- **A document prepared for FDA staff, applicants/sponsors, and public that:**
  - **Describes FDA's interpretation of or policy on a regulatory issue; or**
  - **Relates to**
    - **The design, production, labeling, promotion, manufacturing, and testing of regulated products;**
    - **The processing, content, and evaluation or approval of submissions; and**
    - **Inspection and enforcement policies.**

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Good Guidance Practices

- **Guidance documents do not include documents related to:**
  - Internal FDA procedures
  - Agency reports
  - General information provided to consumers or health professionals
  - Speeches
  - Journal articles and editorials
  - Media interviews and press materials
  - Warning letters
  - Memoranda of understanding
  - Other communications directed to individual persons or firms

Good Guidance Practices

Level I Guidance Documents
(21 CFR 10.115(c)(1))

- Set forth initial interpretations of statutory or regulatory requirements
- Set forth changes in interpretation or policy that are of more than a minor nature
- Include complex scientific issues
- Cover highly controversial issues

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Good Guidance Practices

Level I Guidance Process
(21 CFR 10.115(g))

- Requires a notice of availability in the Federal Register
- Initially issued in draft format and requests public comment before implementation
- After reviewing comments submitted by the public, FDA will issue a final guidance for implementation
- Exception – If the agency determines that prior public participation is not feasible or appropriate, it will concurrently issue the guidance for immediate implementation and request public comment

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Good Guidance Practices

Level 2 Guidance Documents
(21 CFR 10.115(c)(2))

- Set forth existing practices or minor changes in interpretation or policy
- Level 2 guidance documents include all guidance documents that are not classified as Level 1

Good Guidance Practices

Level 2 Guidance Process

- Does not require a notice of availability in the Federal Register
- Is immediately implemented unless FDA indicates otherwise when the document is made available
- Invites public comment
- We review all public comments submitted
- Revise based on any received comments, if appropriate

Good Guidance Practices

Communication with the Public
(21 CFR 10.115(g))

- When considering the development of guidance, FDA may freely discuss issues with the public.
- If the issues to be addressed are particularly complex or controversial, FDA may hold a public meeting, workshop, or advisory committee meeting on the issues before drafting the guidance.
- We may also hold a public meeting after issuing a draft guidance.

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Good Guidance Practices

Communication with the Public
(21 CFR 10.80)

- Once preparation of a draft guidance document has been initiated but has not yet been issued, we (FDA) must not reveal the details of the guidance to "an interested person."
- We may make a draft of a proposed notice available to the public by publication in the Federal Register.
- When the guidance has been issued in draft, we may discuss generally the issues related to the draft guidance; but we must not discuss our specific intentions regarding the final guidance.

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THANK YOU